IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

ERIC J. SCHOENBORN, and
SUZANNE G. SCHOENBORN,

Plaintiff,

v.

STRYKER CORPORATION, and
STRYKER SALES CORPORATION,

Defendants.

Civ. No. 08-1419-AA
OPINION AND ORDER

AIKEN, Chief Judge:

Plaintiffs filed suit alleging products liability and negligence after a medical device known as a "pain pump" was used to administer local anesthetics to plaintiff Eric Schoenborn's shoulder joint after arthroscopic surgery. Plaintiffs seek economic, non-economic, and punitive damages. Defendants Stryker Corporation and Stryker Sales Corporation (collectively Stryker) were the alleged manufacturer and distributer of the pain pump.

Stryker now moves for summary judgment on plaintiffs' claims. Stryker argues that it did not know and could not have known of any

risk associated with the use of pain pumps in the joint space prior to Schoenborn's surgery, and therefore it had no duty to warn of such risk. Stryker also argues that plaintiffs cannot prove that Stryker's alleged failure to warn of such risk caused Schoenborn's injuries, or that plaintiffs are entitled to punitive damages. The motion is denied.

BACKGROUND

Pain pumps are medical devices used to administer prescribed amounts of pain medication directly to a certain area of the body. The marketing, labeling, and sale of pain pumps are regulated by the Food and Drug Administration (FDA). The FDA classifies medical devices into three types: Class I, Class II, and Class III. 21 U.S.C. § 360c. Stryker's pain pumps are Class II devices.

Prior to marketing a new Class II medical device, a manufacturer must obtain Premarket Approval (PMA) for the device, unless an exception applies. See 21 U.S.C. §§ 360c, 360e. As pertinent to this case, the "substantial equivalent" exception permits the marketing of a new Class II device through the premarket notification process, commonly known as the "510(k)" notification process. Id. §§ 360c(f), 360(k). "Under the 510(k) process, if the Class II device is deemed 'substantially equivalent' to a pre-existing device with prior clearance, 'it can be marketed without further regulatory analysis.'" PhotoMedex, Inc. v. Irwin, 601 F.3d 919, 925 (9th Cir. 2010) (quoting

Medtronic, Inc. v. Lohr, 518 U.S. 470, 478 (1996)). "In other words, that device receives '510(k) clearance' and can be put on the market." Id. The 510(k) notification process is much less rigorous than the PMA process and requires no additional testing of the device. Id.; Medtronic, 518 U.S. at 478-79.

In 1999, Stryker began distributing pain pumps manufactured by McKinley Medical, LLC, and in 2000, Stryker acquired the product. In 2002, Stryker introduced a second version of the pain pump which included a programmable computer to regulate the dosage and administration of medication. As with other brands of pain pumps, Stryker's pain pumps are prescription devices sold to health care providers and prescribed by licensed physicians.

The parties agree that at all relevant times, Stryker's pain pumps were cleared through the 510(k) notification process for general surgery applications and "interoperative" use. Notably, McKinley Medical, Stryker, and other pain pump manufacturers had sought 510(k) clearance to market pain pumps for the specific indication of orthopedic use and/or use in the joint cavity. Love Decl., Ex. 4 (Petty Depo., p. 152); Exs. 29-31. Ultimately, the FDA determined that a substantially equivalent predicate device with this specific indication did not exist and did not give clearance to market the pain pumps for use in the joint space. Love Decl., Ex. 4 (Petty Depo., p. 152). Rather, the FDA cleared the Stryker pain pumps for the general indication of "intra-

operative" use. Hoffman Decl., p. 2. Plaintiffs maintain that Stryker nonetheless continued to market and sell its pain pump for use directly in the joint space, in violation of FDA regulations. Stryker denies these allegations.

On November 8, 2004, Schoenborn underwent arthroscopic surgery on his shoulder, and his surgeon used a Stryker pain pump device to administer local anesthetics for up to 72 hours following surgery.[1] Schoenborn's surgeon, Dr. Isaacson, placed the pain pump catheter directly into Schoenborn's shoulder joint to deliver the prescribed pain medication. Subsequently, Schoenborn developed glenohumeral chondrolysis, a very rare and painful condition involving the rapid and permanent destruction of articular cartilage in the shoulder joint.

On December 5, 2008, plaintiffs filed suit. Plaintiffs maintain that Stryker was on notice that the use of pain pumps to deliver pain medication directly to the shoulder joint could cause harm, and that Stryker nonetheless marketed its pain pumps for such use and failed to warn physicians that pain pumps had not been cleared for such use by the FDA.

DISCUSSION

Stryker moves for summary judgment on grounds that plaintiffs

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[1]Stryker contends that no evidence establishes the use of Stryker's pain pump during Schoenborn's surgery. However, plaintiff presents evidence that identifies Stryker's pain pump. Love Decl., Ex. 2, p. 1.

fail to present any evidence that, at the time of Schoenborn's surgery, the scientific or medical community had reason to know of risks associated with using pain pumps to administer local anesthetics directly to the joint space. Stryker emphasizes that under Oregon law, a manufacturer's duty to warn is limited to the dangers of which it knew or reasonably should have known. See McEwen v. Ortho. Pharm. Corp., 270 Or. 375, 385-86, 528 P.2d 522 (1974) (drug manufacturer has duty "of making timely and adequate warnings to the medical profession of any dangerous side effects produced by its drugs of which it knows, or has reason to know"). Thus, Stryker maintains that because it did not have reason to know of any association between pain pump use and chondrolysis as of November 2004, plaintiffs cannot prevail on their products liability or negligence claims.[2] I disagree and find material issues of fact preclude summary judgment.

Though not overwhelming, plaintiffs present some evidence that Stryker knew or should have known of toxicity concerns associated with the administration of local anesthetics directly into the joint area. Plaintiffs cite to an article published in 1985 that

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[2]As Stryker notes in its Motion to Submit Supplemental Briefing, plaintiffs' counsel has taken the position in other pain pump litigation that a strict products liability claim based on a failure to warn does not require that the manufacturer knew or should have known of the alleged risk of harm. Given that I find questions of fact regarding Stryker's actual or constructive knowledge, I need not address this issue and find Stryker's motion moot.

discusses the toxicity of local anesthetics to articular cartilage. See Love Decl., Ex. 20 (Nole, et al., *Bupivacaine and Saline Effects on Articular Cartilage*, ARTHROSCOPY: J. ARTHROSCOPIC & RELATED SURG. (1985)). Stryker emphasizes that plaintiffs fail to present expert testimony or opinion regarding the significance of the Nole article and argues that the court should not rely on the interpretation of plaintiffs' counsel when they are not qualified to render expert opinion. See Monroe v. Zimmer U.S. Inc., ___ F. Supp. 2d ___, 2011 WL 534037, at *19 (E.D. Cal. Feb. 14, 2011) ("The court cannot accept *counsel's* interpretation of the medical literature, counsel's unsupported determination that defendants had a duty to investigate the medical literature, nor counsel's unsupported determination that the medical literature triggered defendants' alleged duty to 'further investigate [the] risk or at least warn of [the] risk.'") (quoting the plaintiff's memorandum in opposition to summary judgment).

If plaintiffs relied solely on the Nole article to establish Stryker's actual or constructive knowledge, I might find Stryker's argument more persuasive.[3] However, plaintiffs also present internal documents of Stryker discussing the lack of FDA clearance or approval for "inter-articular injection" of a certain pain

[3]I also note that while Styker's objection is well-founded, the record contains expert reports that cite the Nole article to support opinions of causation. See, e.g., doc. 108; Cox v. DJO, LLC, Civ. No. 07-1310-AA, doc. 418 (Ex. 1, pp. 5-12), doc. 492 (Exs. 66, 67).

medication and referencing anesthetic "toxicity" concerns associated with pain pump use. Love Decl., Exs. 8, 10, 11 (doc. 193; filed under seal). Stryker maintains that these documents are not relevant and "say nothing about the only form of toxicity relevant here - chondrotoxicity" and objects to the consideration of such evidence on that ground. Stryker's Reply to Pls.'s Concise Statement of Material Facts, p. 2 (reply to SMO 4e, 4f); Styker's Evid. Obj. to Pls.'s Response, pp. 4-5 (Objections 7, 8). I overrule Stryker's objection and find the documents relevant. The type of toxicity to which the documents reference is a factual finding not appropriate for this court to make on summary judgment.[4]

Finally, plaintiff's evidence must be considered in the context of Stryker's and other manufacturers' attempts to gain 510(k) clearance to market the pain pumps for use in the joint space, the FDA's determination that no predicate device established the efficacy and safety of such use, and Stryker's continued promotion of the pain pumps for use in the joint space. Construing all inferences in favor of plaintiffs, they present sufficient evidence to create a genuine issue of material fact as to whether Stryker should have known or anticipated that the administration of local anesthetics directly into the shoulder joint was toxic or

[4]Stryker also objects to these documents on hearsay grounds. However, the documents are not offered to prove the truth of the matter asserted but to show notice.

otherwise harmful. Monroe, 2011 WL 534037, at *22-23; Hamilton v. Breg, Inc., 2011 WL 780541, at *3-5 (D. Ohio Jan. 20, 2011); Koch v. Breg, Inc., 2010 WL 5301047, at *2-4 (D.S.D. Dec. 20, 2010). It is not incumbent on plaintiffs to show that Stryker should have known of the specific injury or damage - chondrolysis - allegedly caused by the use of the pain pumps.

I recognize that several courts have held otherwise and found that any danger from intra-articular pain pump use was "not knowable" prior to 2005 or 2006. Rodriguez v. Stryker Corp., 2011 WL 31462, at *8 (M.D. Tenn. Jan. 05, 2011); see also Krumpelbeck v. Breg, Inc., 759 F. Supp. 2d 958, 974 (S.D. Ohio 2010); Pavelko v. Breg, Inc., 2011 WL 782664, at *5-6 (D. Colo. Feb. 28, 2011); Phillippi v. Stryker Corp., 2010 WL 2650596, at *3 (E.D. Cal. July 1, 2010); Meharg v. I-Flow Corp., 2010 WL 711317, at *3-4 (S.D. Ind. Mar. 1, 2010). I respectfully disagree with those decisions and instead find this question appropriate for the trier of fact. It may well be that plaintiffs' evidence at trial will fail to show by a preponderance that Stryker had reason to know of the risks associated with intra-articular pain pump use. As noted by one district judge, "[t]he medical evidence that pain pumps could cause chondrolysis was at best fragmentary at the time" of Schoenborn's surgery. Hamilton, 2011 WL 780541, at *3. On a motion for summary judgment, however, all inferences must be construed in favor of plaintiffs. So construed, genuine issues of material fact remain.

Stryker also contends that plaintiffs cannot show any alleged failure to warn by Stryker caused Schoenborn's injury. Vaughn v. G.D. Searle & Co., 272 Or. 367, 369, 536 P.2d 1247 (1975). Stryker emphasizes Dr. Isaacson's deposition testimony stating that she did not read the Instructions for Use accompanying the Stryker pain pump prior to Schoenborn's surgery or rely on statements from Stryker's sales representatives, placing into question whether Stryker's alleged failure to warn could have caused Schoenborn's injury. Horwitz Decl., Ex. R (Isaacson Depo., pp. 45-48, 55). However, Dr. Isaacson's testimony must be considered in the context of Stryker's marketing strategies, along with her sworn statement that she would not have used pain pumps to administer anesthetics directly to the joint space if she had known the FDA had not cleared the pain pumps for such use. Love Decl., Ex. 1. Although Stryker objects to Dr. Isaacson's statement as "speculative," given the circumstances as a whole, I do not find it so speculative as to warrant its exclusion.

Finally, Stryker moves for summary judgment regarding plaintiffs' prayer for punitive damages. As with other pain pump cases, plaintiffs here present little evidence that Stryker had actual knowledge of the risk of harm allegedly caused by pain pumps at the time of Schoenborn's surgery, such that Stryker acted with "malice" or a "reckless and outrageous indifference to a highly unreasonable risk of harm" and with "conscious indifference to the

health, safety and welfare of others" by marketing its pain pumps for intra-articular uses. Or. Rev. Stat. § 31.730(1); Andor v. United Air Lines, Inc., 303 Or. 505, 517, 739 P.2d 18 (1987) (punitive damages "are a penalty for conduct that is culpable by reason of motive, intent, or extraordinary disregard of or indifference to known or highly probable risks to others"). However, as explained above, the extent of Stryker's knowledge is a question of fact, and I decline to grant summary judgment at this time.

CONCLUSION

Stryker's Motion for Summary Judgment (doc. 170) is DENIED, and Styker's Motion for Leave to Submit Supplemental Briefing (doc. 201) is DENIED as moot.

IT IS SO ORDERED.

DATED this 11th day of July, 2011.

Ann Aiken
United States District Judge